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Original Research Article.

Efficacy And Safety of Montelukast Sodium 10 Mg (Mubact 10) in Adult Patients with Asthma: A Post-Marketing Surveillance Study in Iraq (The MIRAQ Study)

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ABSTRACT

Introduction: Asthma is a chronic inflammatory respiratory disease that often remains inadequately controlled, despite the use of inhaled corticosteroids (ICS). Montelukast, an oral leukotriene receptor antagonist (LTRA), is recommended as an add-on or alternative therapy for asthma. This study aimed to evaluate the real-world efficacy and safety of montelukast sodium 10 mg as add-on therapy in adult Iraqi patients with mild-to-moderate persistent asthma.

Methods: This prospective, multicenter, observational post-marketing surveillance study enrolled 551 adult patients with mild-to-moderate persistent asthma. As part of routine clinical care, patients were prescribed montelukast 10 mg (MUBACT 10) once daily for 4 weeks alongside their existing asthma treatment. Clinical outcomes included changes in four key asthma symptoms – wheeze, cough, activity limitation, and sleep disturbance; patient and physician satisfaction; and adverse events (AEs).

Results: All four asthma symptoms showed statistically significant improvement by visit 2 at (week 4 / end of treatment) ($p < 0.001$). The proportion of patients reporting no wheeze increased from 6.9% to 86.0%, and no cough from 5.3% to 76.2%. Reports of no activity limitation rose from 14.3% to 85.7%, and normal sleep from 16.2% to 88.6%. Treatment satisfaction improved substantially among physicians (very satisfied: 10.9% to 39.0%) and patients (7.1% to 30.9%). AEs occurred in 10.2% of patients, mostly mild and self-limiting.

Conclusion: Treatment with montelukast sodium 10 mg (MUBACT 10) demonstrated significant improvements in asthma control and quality of life with good tolerability, supporting its use as an efficacious add-on therapy in real-world clinical practice in Iraq.

Keywords: Asthma, Iraq, Leukotriene Receptor Antagonist, Montelukast, Real-world Efficacy.

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INTRODUCTION

Asthma is a chronic, complex, non-communicable respiratory disease that affects individuals across all age groups.[1] It is characterized by persistent airway inflammation and manifests through recurrent episodes of coughing, wheezing, breathlessness, and chest tightness.[2] The global burden of asthma has been steadily rising, contributing to increasing rates of

hospitalizations and mortality.[3] Both the prevalence and severity of asthma vary widely, influenced by a combination of genetic predisposition and environmental exposures.[4]

Currently, asthma affects approximately 300 million people worldwide and is associated with nearly 1,000 deaths per day.[5] In 2019 alone, it was estimated that 262 million individuals were living with asthma, contributing to approximately 455,000 deaths globally.[1] In Iraq, the disease burden is similarly significant, with a prevalence of asthma around 10.5%, emphasizing the urgent need for effective and accessible management strategies.[3]

Asthma significantly impairs quality of life, particularly in low- and middle-income countries, where underdiagnosis and undertreatment are common. Many individuals with asthma experience sleep disturbances, daytime fatigue, and difficulties with concentration, often due to suboptimal disease control.[1]

According to current asthma management guidelines, inhaled corticosteroids (ICS) are the cornerstone of asthma treatment, recommended as first-line therapy to control symptoms and prevent exacerbations.[5,6] However, despite the effectiveness of ICS, asthma control remains inadequate in many patients, often due to poor adherence to treatment.[7] This highlights the need for adjunctive therapies alongside ICS to achieve better treatment outcomes.

Leukotriene receptor antagonists (LTRAs), such as montelukast, offer a convenient oral treatment option for asthma and have demonstrated the ability to reduce reliance on ICS and mitigate long-term corticosteroid-related side effects.[8] The Global Initiative for Asthma (GINA) 2025 guidelines include LTRAs as an option for maintenance therapy.[5] Similarly, the British Thoracic Society (BTS), National Institute for Health and Care Excellence (NICE), and Scottish Intercollegiate Guidelines Network (SIGN) recommend LTRAs as an add-on therapy when asthma remains uncontrolled on low-dose maintenance and reliever therapy, especially in patients without elevated fractional exhaled nitric oxide (FeNO) and eosinophilic levels.[6] The 2020 Asthma Management Guidelines also recommend LTRA and a combination of ICS and LTRA as alternative choices for step 2 and step 3 treatment of persistent asthma, respectively.[9] Reflecting these global standards, the Primary Health Care Service Delivery Guidelines for Iraq also recommend montelukast as a controller medication for patients with mild persistent asthma.[10]

Montelukast, a cysteinyl LTRA, acts by inhibiting bronchoconstriction and attenuating inflammation, making it an effective treatment option for chronic asthma.[11-14] Montelukast is approved for the treatment of chronic asthma in individuals aged 6 years and older.[15] It is found to be beneficial for improving the quality of life in patients with mild-to-moderate persistent asthma.[8] Montelukast monotherapy has also proven to be an effective alternative to low-dose ICS in the management of mild asthma.[16,17] Although several studies have established the clinical efficacy of montelukast as an add-on therapy in asthma,[18,19] there is a relative paucity of post-marketing surveillance (PMS) data examining its real-world effectiveness and safety, particularly in the Iraqi population. Therefore, this MIRAQ observational study was conducted to evaluate the real-world efficacy and safety of montelukast sodium 10 mg as an add-on therapy to standard asthma controller treatment in adult patients with mild-to-moderate persistent asthma in Iraq.

METHODS

Study Design

This was a prospective, multicenter, open-label, non-comparative, observational, PMS study conducted across various hospitals and clinics in Iraq. The study aimed to evaluate the real-world efficacy and safety of MUBACT 10 tablets (montelukast sodium 10 mg) in adult patients with asthma over a treatment period of four weeks. The study was conducted from 01/APR/2024 to 31/JUL/2024 in Iraq.

Study Population

Adults of any sex, aged ≥18 years, were eligible to participate in the study if they had mild-to-moderate persistent asthma that was not adequately controlled with ICS and if “as-needed” short-acting β-agonists did not provide adequate symptom relief. Patients requiring montelukast 10 mg tablets as part of routine clinical care were eligible for enrolment. Patients were excluded if they had severe asthma or known hypersensitivity to montelukast or any other component of MUBACT 10 mg tablets or had any other condition that was considered a risk factor by the doctor associated with the study.

Ethical Considerations

Investigators conducted the study in accordance with local regulatory guidelines and ethical principles consistent with the Declaration of Helsinki.

Treatment Exposure

All enrolled patients were prescribed montelukast sodium 10 mg once daily as part of their routine clinical care, in accordance with national and international asthma management guidelines. Montelukast 10 mg therapy was initiated at the discretion of the treating physician prior to patient enrolment, independent of the study protocol. No modifications were made to patients' existing asthma management plans apart from the addition of montelukast 10 mg tablet, where clinically indicated.

Data Collection and Study Procedure

Data was collected using a standardized patient case record form (CRF). The CRF documented patient demographics, baseline clinical details, concomitant medications, and clinical history (e.g., allergic rhinitis, family history of asthma, seasonal or exercise-induced asthma, and smoking status).

Patients were evaluated at two time points:

- Visit 1 (Day 0 / baseline): Eligibility check, baseline clinical assessment, and initiation of montelukast sodium 10 mg tablets
- Visit 2 (Week 4 / end of treatment): Final clinical assessment and safety evaluation

Any unplanned visits and treatment discontinuations were also recorded. Patients were instructed to report any adverse events (AEs) experienced during the treatment period.

OUTCOME MEASURES

Efficacy Assessment

A composite clinical assessment score using a structured 4-point ordinal scale was used to evaluate asthma symptoms: wheeze, cough, activity limitation, and sleep disturbance. Each parameter was scored from 0 to 3, with higher scores reflecting greater severity of symptoms. For wheeze, a score of 0 indicated no wheezing, 1 denoted some wheeze, 2 represented medium wheeze, and 3 indicated severe wheeze. Cough was similarly scored, with 0 indicating no cough, 1 reflecting occasional cough,

2 representing frequent coughing episodes, and 3 denoting continuous coughing. Activity limitation was evaluated based on the extent to which symptoms restricted physical functioning: a score of 0 indicated no limitation, 1 referred to the ability to run a short distance or climb up to three flights of stairs, 2 indicated the ability to walk only, and 3 was assigned when patients missed work or stayed indoors due to symptom severity. Sleep disturbance was also rated on a scale of 0 to 3, where 0 indicated normal, uninterrupted sleep, 1 reflected a generally restful night with slight wheeze or cough, 2 denoted disturbed sleep with awakening two to three times, and 3 indicated a poor night's sleep with frequent awakenings. Symptom scores were recorded at both Visit 1 (baseline) and Visit 2 (end of treatment).

Satisfaction levels of both physicians and patients were assessed using a 5-point Likert scale designed to capture subjective impressions related to treatment effectiveness and overall experience. Respondents were asked to rate their level of satisfaction as very dissatisfied, dissatisfied, neutral, satisfied, or very satisfied, corresponding to ordinal scores from 1 to 5, respectively. This scale was administered at two time points, Visit 1 (baseline) and Visit 2 (end of treatment), to evaluate changes in satisfaction over the course of treatment.

Safety Assessment

AEs reported during the 4-week treatment period were documented. The type, nature (mild/moderate/severe), and associated treatment discontinuation were recorded. Patients were advised to report any unusual symptoms immediately, even prior to the scheduled follow-up.

Statistical Analysis

All data were entered in Microsoft Excel, and all statistical analyses were conducted using IBM SPSS Statistics version 23.0 and cross-verified for consistency. Descriptive statistics were used to summarize patient demographics and baseline clinical characteristics. Continuous variables (e.g., age and weight) were presented as mean ± standard deviation. Categorical variables (e.g., sex and comorbidities) were summarized as frequencies and percentages (n, %). The primary efficacy endpoint was the physician-assessed level of clinical improvement in asthma symptoms. The number of patients in each improvement category was calculated and expressed as counts and percentages (n, %). Visit-wise frequency distributions for each score were tabulated for each parameter. Comparisons between visit 1 and visit 2 were conducted using the Chi-square test to evaluate changes in symptom severity.

Safety was assessed based on the incidence of treatment-emergent AEs reported during the 4-week follow-up. AEs were recorded and categorized by type, frequency, and severity.

Data from all participating centers were pooled and analyzed. No formal hypothesis testing was performed, in line with the non-comparative nature of the study. All statistical tests were two-tailed, and p-value <0.05 was considered statistically significant.

RESULTS

Patient Disposition and Baseline Characteristics

A total of 1050 adult patients with mild-to-moderate persistent asthma were screened in the study by 70 physicians across different regions of Iraq. A total of 551 adult patients with mild-to-moderate persistent asthma were enrolled and completed the 4-week treatment period. The details of the patients' flow through the study are provided in Fig. 1.

The mean age of the participants was 34.6 ± 13.2 years. A majority of them reported a history of exercise-induced asthma (52.3%), allergic rhinitis (60.4%), or a family history of asthma (59.3%). Details of the baseline characteristics of study patients are presented in Table 1.

EFFICACY OUTCOMES

Change in Clinical Symptoms

All four asthma symptoms assessed showed statistically significant improvement between visit 1 and visit 2. At visit 1, 42.5% and 42.3% of patients had "some" or "medium" wheeze, respectively. At visit 2, 86% reported no wheeze, and no patient had severe wheeze. Similarly, cough severity improved, with 76.2% reporting no cough at follow-up, compared to only 5.3% at baseline.

Activity limitation also improved markedly by visit 2. While only 14.3% of patients reported no limitation at baseline, this increased to 85.7% by visit 2. Sleep quality followed a similar trend, with 88.6% of patients sleeping "fine" after 4 weeks of treatment, up from 16.2% at baseline. All improvements were statistically significant with $p < 0.001$ across all parameters (Chi-square test).

The details of the changes in clinical symptoms are provided in Fig. 2.

Physician and Patient Satisfaction

At baseline, 30.9% of physicians and 51.7% of patients were neutral regarding treatment satisfaction (see Fig. 3). Only 10.9% of physicians and 7.1% of patients were "very satisfied". After 4 weeks, the proportion of physicians and patients who were "very satisfied" increased to 39% and 30.9%, respectively. The changes were statistically significant ($p < 0.001$, each).

Safety Outcomes

Among 551 patients, 56 (10.2%) reported at least one AE. The most frequently reported adverse events were abdominal pain (3.4%), respiratory tract infections (5.1%), and headache (1.7%). A majority of the patients (89.8%) did not experience any AEs, 7.3% of patients reported mild AEs, 2.4% patients reported moderate AEs, and 0.5% of patients reported severe AEs. No serious adverse drug reactions were reported, and all events resolved without sequelae.

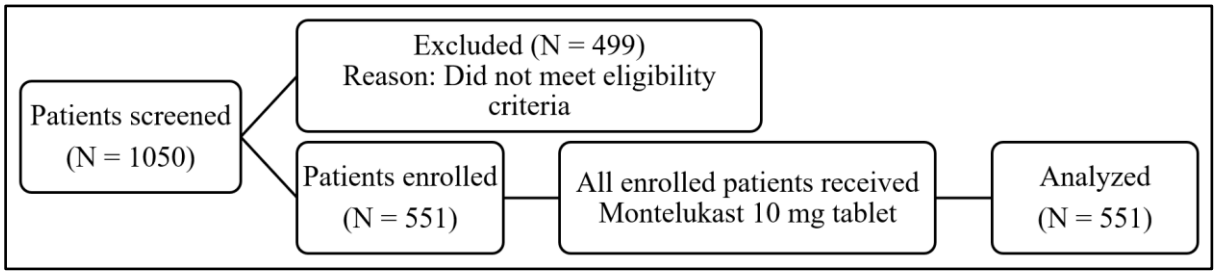

Figure 1: Patient flow through the study

Table 1: Baseline characteristics of study patients (N = 551)

Characteristic	Data*
Age (mean ± SD)	34.6 ± 13.2
Weight (mean ± SD)	75.4 ± 13.7
Sex	
Male	343 (62.3%)
Female	208 (37.7%)
Population	
Rural	347 (63.0%)
Urban	204 (37.0%)
History of exercise-induced asthma	288 (52.3%)
History of allergic rhinitis	333 (60.4%)
Family history of asthma	327 (59.3%)
Seasonal asthma	358 (65.0%)
Smoking	177 (32.1%)
Inhaled corticosteroid use	220 (39.9%)
Short-acting β_2-agonist use	148 (26.9%)
Other asthma treatments	551 (100.0%)

SD, standard deviation.

**Data presented as frequency (%), unless otherwise specified.*

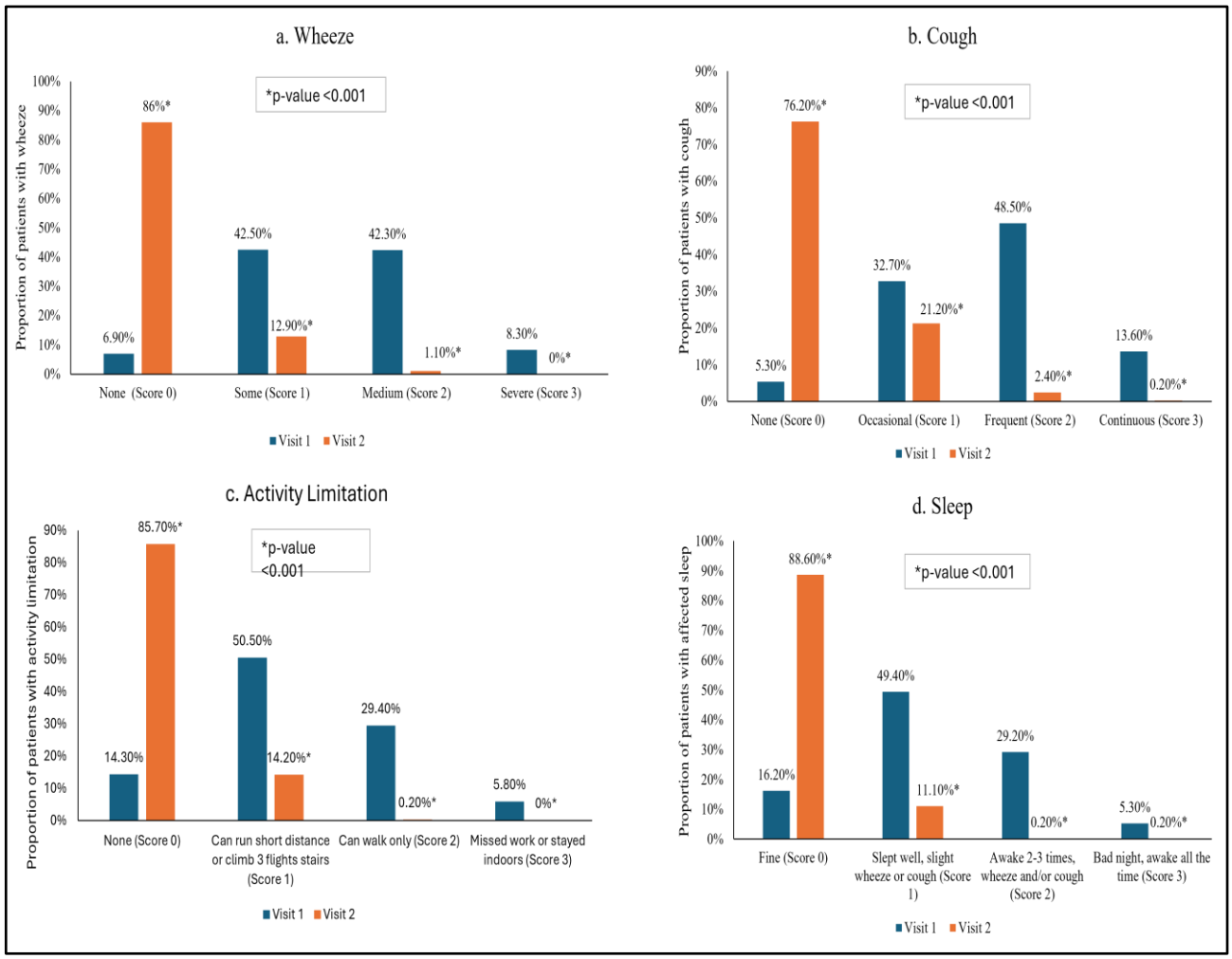

Figure 2: Change in clinical assessment parameters from baseline (Visit 1) to after treatment (Visit 2) (N = 551)

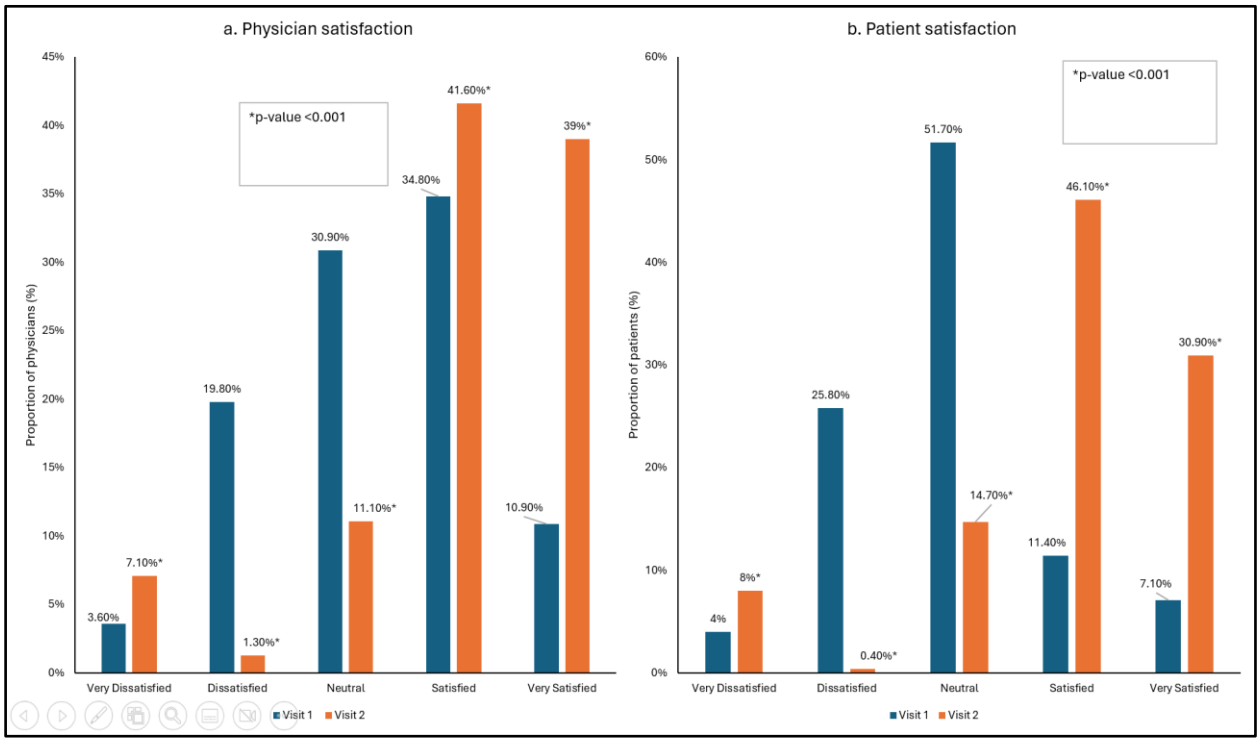

Figure 3: Satisfaction rates at baseline (Visit 1) and after treatment (Visit 2)

DISCUSSION

This prospective observational study evaluated the real-world efficacy and safety of montelukast sodium 10 mg as an add-on therapy in adult Iraqi patients with mild-to-moderate persistent asthma. After 4 weeks of treatment, patients reported significant improvements in asthma symptoms, activity limitation, and sleep quality. Furthermore, both physician and patient satisfaction with asthma control increased substantially, with no serious adverse drug reactions reported.

The observed improvements in clinical symptoms such as wheeze, cough, sleep, and activity limitation align well with findings from earlier controlled trials and real-world studies. For instance, Al-Hamdani FY et al. demonstrated that montelukast significantly reduced wheezing, coughing, and asthma symptom scores in Iraqi patients after one month of therapy, with greater efficacy than ketotifen.[15] In our study, wheeze was resolved in 86% of patients and cough was resolved in 76.2% after 4 weeks, suggesting the potential role of montelukast in symptom resolution even outside controlled environments.

Similarly, the results are consistent with those reported by Ikram A et al., who found that montelukast monotherapy significantly improved quality of life scores across multiple domains, including symptom control and activity limitation, in Pakistani patients with mild-to-moderate persistent asthma.[14] Our findings showed comparable benefits in two key indicators of daily functioning and overall quality of life, with 85.7% of patients reporting no activity limitations and 88.6% reporting undisturbed sleep after 4 weeks of treatment.

The enhanced treatment satisfaction among physicians and patients in our study also supports prior work by Baig S et al., who reported statistically significant improvement in quality of life using validated tools such as the Asthma Quality of Life Questionnaire - Standard (AQLQ-S) in patients treated with montelukast as compared to patients treated with placebo ($p = 0.02$).[8] In our study, the proportion of patients who were "very satisfied" rose from 7.1% at baseline to 30.9% after treatment, and physician satisfaction mirrored this trend.

Furthermore, the AEs in our study, such as headache and abdominal pain, align with those documented in earlier studies on montelukast, further reinforcing its well-established safety profile.[20,21] The mild and self-resolving nature of AEs is also consistent with the published data from randomized controlled trials where montelukast was well tolerated and showed minimal systemic side effects.[12,14]

The baseline characteristics of the study population were consistent with known asthma risk factors reported in Iraqi epidemiological studies. As per Alsajri AH et al., allergic rhinitis, family history, and smoking were significantly associated with asthma prevalence. These findings echoed in our study, where over 60% of patients had a history of allergic rhinitis and nearly 60% had a family history of asthma. These comorbidities further justify the consideration of LTRA therapy, which targets inflammatory pathways involved in allergic responses.[3,8]

Taken together, the results of this PMS study contribute meaningful real-world evidence supporting the use of montelukast in the Iraqi population with asthma. Given its oral administration, favorable safety profile, and efficacy in improving asthma control and patient satisfaction, montelukast represents a valuable therapeutic option, particularly in low-resource settings where adherence to ICS or access to inhalers may be limited.[7]

LIMITATIONS AND FUTURE DIRECTIONS

Despite its strengths, this study has some limitations. The study was limited to a 4-week follow-up period, which may not capture long-term safety or control of asthma. The absence of spirometric data or validated quality-of-life instruments such as the Asthma Control Test or AQLQ-S limits direct comparison with global trials. Future research should include longer-term follow-up and standardized patient-reported outcome measures.

CONCLUSION

This study demonstrates that montelukast sodium 10 mg, when used as add-on therapy in adult Iraqi patients with mild-to-moderate persistent asthma, is associated with notable improvements in asthma symptoms, daily functioning, and treatment satisfaction, while maintaining a favorable safety profile. These findings align with global and regional studies and support the potential use of montelukast in asthma management in real-world settings.

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Conflict of Interest: None Declared.

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